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SUMMARY OF SAFETY AND EFFECTIVENESS

QUEST MYOCARDIAL PROTECTION SYSTEM

I. General Information

A. Generic Name:	Cardioplegia Delivery System
B. Trade Name of Device:	Quest Myocardial Protection System
C. Applicant's Name and Address:	Quest Medical, Inc. One Allentown Parkway Allen, Texas.
D. Pre-market Notification Number:	Not assigned to date

II. Indications For Use

The Quest MPS consisting of a control unit, associated disposable cassette sets with a heat exchanger, additive cassettes, and extension sets used together are indicated for delivery of cardioplegic solutions to the heart during open heart surgery

III. Device Description

The Quest MPS device consists of a microprocessor based system for monitoring and controlling the mixing, pumping, pressure, and the heating and cooling of cardioplegia solutions. Sterile disposables are part of the system as well as pumping cassettes, and a heat exchanger with an integral bubble trap. The MPS includes a primary pump where blood crystalloid solutions are mixed at defined ratios, and two secondary pumps for the addition of an arresting agent and other physician-defined additives. The device also contains a water circulation system for supplying warm or cold water to the heat exchanger to achieve user-defined cardioplegia temperatures.

IV. Device Classification: Class II.

Classification:
Myocardial Management System™ (MPS) with Heat Exchanger are reviewed by the FDA Cardiovascular (CV) and (HO) General Hospital Classification Panels. The Product Classification Codes and Panel Codes for this device and predicate devices are:

80 DWK Pump, Infusion, Cardiovascular
74 DTR Cardiopulmonary Bypass, Heat Exchanger
74 DXS Gauge, Pressure, Coronary Cardiopulmonary Bypass
74 KRL Cardiopulmonary, Bypass Bubble Detector
74 DRS Transducer, Blood-Pressure, Extravascular
74 DWF Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing

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V. Safety and Effectiveness

Substantial Equivalence:

The device has been shown to be substantially equivalent to the Sarns' Integrated Cardioplegia Delivery System (ICDS) #K810079, Sarns Conducer Heat Exchanger # K923311, Avecor Heat Exchanger # K904171, Stockert-Shiley Low Level Detector Bubble Monitor # K864619, Shiley Temperature Monitor # 802147and the Stockert-Shiley Dual Pressure Control Module # K862836.

VI. Other Safety and Effectiveness Data:

Materials: Fluid contact materials of construction comply with ISO-10993 " Biological Evaluation of Medical Devices - Part 1 : Evaluation and Testing" for short term devices.
Sterilization: Validated METHOD-1 Radiation Sterilization SAL 10^{-6}
Pyrogenicity: Non-Pyrogenic per USP Pyrogen test (LAL)

Functional Testing

Leak Test Requirements	No leaks at 15 psi.
Pull Test Requirements	No leaks at 5 lbs for small bore and 10 psi for large bore tubing.
Luer Connections	Meets ANSI/HIMA MD70.1-1983 for Medical Materials Luer Taper Fittings.
Package Integrity	Tyvek/Polystyrene tray and Tyvek/Polymylar pouches passed burst test with in accordance with ASTM F1140-88.
Shipping and Distribution Testing	Passed Distribution Simulation Test I/NSTA Project 1A. ASTM D-775-80 and D-999-75.
Accelerated Aging	One (1) year with no effects on performance characteristics.
Heat Exchanger Corrosion Test	Resists corrosion for periods of up to 72 hours.
Air In-line Detection	Detects 100μL size air bubbles in blood and saline.
Hemolytic Characteristics	MPS disposable and instrument lower than predicate devices.
Level Sensing and Autoventing	Meets performance specifications for venting and is equivalent to the predicate device for level sensing
Pressure Control Delivery	Allows greater control of pressure than does the predicate device.

Pressure Alarm Verification	Operates within predicate device's alarm range of 0% to ± 10% of preset value. Allows ability to set lower pressure limits.
Pressure Sensor Accuracy	Equivalent to predicate device specification of ± 5 mmHg.
Pump Performance at Temperature Extremes	MPS has a mean accuracy of 95% of the flow rates (50, 150, 500 ml/minute) delivered at 36°C and 5°C.
Use with Crystalloid Filter	Pressure cuffs allow MPS to provide maximum settable flow rate with the use of a crystalloid filter.
Arrest Agent/Additive Concentration Delivery	Adjustable from 4-40 mEq/L and delivers within ± 10% of desired concentration.
Blood/Crystalloid Ratio Accuracy	Less than 3% of each components required proportion
Delivery Rate Accuracy	Meets AAMI recommended 5% accuracy specification for infusion pumps.
Pump Output Flow Profile	Depicts a more linear flow rate than the predicate device at 50, 300, 500 ml/minute.
Environmental Tests	Meets temperature, humidity specification requirements and UL External Surface Temperature Safety requirements.
Electrical Safety	Meets UL/CSA requirements for electrical safety
Temperature Sensor Accuracy	Meets temperature sensor accuracy specifications of 5% of the reading.
Warm and Cold Temperature Control	Heat and cools cardioplegia solution within operating flow rate ranges.